



Araim Pharmaceuticals' Cibinetide (ARA 290) Regenerates Small Nerve Fibers and Improves Neuropathic Clinical Symptoms in the Orphan Disease of Sarcoidosis

TARRYTOWN, NY, May 8, 2017. **Araim Pharmaceuticals Inc.**, today announced the publication of Phase 2b study results in small fiber neuropathy of the Company's lead compound within the Innate Repair Receptor activator platform (doi:10.1167/iovs.16-21291). Cibinetide demonstrated significant nerve regrowth assessed by two different measures of nerve fiber regeneration, as well as reductions in pain and improvements in functional capacity.

The double blind, randomized, placebo-controlled, two-center study published in *Investigative Ophthalmology & Visual Science* assessed the safety and efficacy of daily subcutaneous 1, 4, 8 mg cibinetide or placebo for 28 days in 64 patients with painful sarcoid neuropathy. Cibinetide met its pre-specified primary efficacy endpoint: to assess small nerve fiber loss and repair as quantified by corneal confocal microscopy (CCM). A significant increase in corneal nerve fiber area versus placebo was noted for cibinetide 4 mg dose, a treatment effect corresponding to $\approx 23\%$ increase from baseline. Cibinetide nerve regenerative effects were also demonstrated by a significant increase in skin intraepidermal growth associated protein-43 nerve fiber length. Improved patient functional activity was correlated with the increase in nerve fibers, and clinically meaningful placebo-corrected decreases in pain intensity were noted in patients with moderate to severe pain at baseline. No significant safety issues were observed for any treatment group in the trial.

"There are no approved therapies to treat the underlying pathophysiology in neuropathy, and current symptomatic treatment options for patients suffering from the extremely debilitating and painful disease of sarcoidosis are often ineffective and/or injurious," commented Dr. Daniel Culver of The Cleveland Clinic, the principal investigator of the trial and lead author of the paper. "The magnitude of effect in only 28 days is remarkable, and suggests that cibinetide has the potential to become a transformative disease modifying therapy for sarcoidosis patients as well as for other diseases characterized by chronic inflammation and persistent tissue injury."

"We are excited about the trial's positive results which were the basis for a recently-completed successful end-of-phase 2 meeting with the FDA. We look forward to taking the next step in clinical development for both neuropathic pain and disease modification indications. As cibinetide has also demonstrated positive results for both nerve regeneration and symptomatic improvements in diabetic peripheral neuropathy, our clinical program will include a broad neuropathic population," said Dr. Daiva Bajorunas, Chief Medical Officer of Araim.

About Sarcoidosis

Sarcoidosis^{i, ii, iii} is a chronic systemic granulomatous disease of unknown etiology, affecting young-to-middle-age individuals. The disease is chronic and progressive in more than a third of cases, leading to clinically significant organ impairment, including small nerve fiber loss, and significant, disabling neuropathic symptoms, with pain as the most common complaint. While variable for each patient, the symptoms often cause major loss in quality of life and inability to participate in the work force. Morbidity in sarcoidosis is significant and multifactorial. Mortality is infrequent, but may be increasing over the years.

About Araim Pharmaceuticals, Inc.

[Araim Pharmaceuticals, Inc.](http://www.araimpharma.com) is a clinical stage drug development company with a novel platform technology designed to address devastating injuries and chronic diseases underserved by current therapies. With their discovery of the Innate Repair Receptor (IRR), Araim has identified the target for activating tissue repair and recovery from inflammatory and other injuries. Their novel peptide library of IRR specific ligands activates tissue protective, reparative and anti-inflammatory signaling pathways. Araim has an ongoing, active and promising preclinical program in a wide array of conditions involving tissue damage and repair, including neuropathy, cardiovascular damage, diabetes complications, wound healing and aging. Cibinetide is a first-in-class synthetic 11-amino acid peptide IRR agonist. The most advanced clinical program with cibinetide is in sarcoidosis-related small fiber neuropathy. Cibinetide has been granted US and EU Orphan Drug Designation for the treatment of sarcoidosis, and has received US Orphan Drug and Fast Track designations for the treatment of neuropathic pain in patients with sarcoidosis. Cibinetide was granted EU Orphan Medicinal Product designation for prevention of graft loss in pancreatic islet transplantation, and US Orphan Drug Designation for treatment to increase survival and improve functioning of pancreatic islets following transplantation. A pilot study evaluating the safety and efficacy of cibinetide in diabetic macular edema is currently ongoing at Queen's University Belfast. www.araimpharma.com

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